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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,236	11/05/2003	Donald Hetzel	SENS0002	7940

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GLENN PATENT GROUP
3475 EDISON WAY, SUITE L
MENLO PARK, CA 94025

EXAMINER	
SIMS, JASON M	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/702,236	HETZEL ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8-17, 21-26, 28-30, 32, and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *17* is/are allowed.

6)☒ Claim(s) *1-6,8-16,21-26,28-30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 9/18/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 9/18/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-6, 8-17, 21-26, 28-30, 32, and 33 are the current claims hereby under examination.

Terminal Disclaimer

The terminal disclaimer filed on 9/18/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of application 10/702210 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112-First

The following rejection is being newly applied and has been necessitated by amendment:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 15, and 33 and all claims dependent therefrom are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment to the claims to classify a state of glucose metabolism disorder, "wherein said state of glucose metabolism disorder comprises a chronic condition" and wherein the condition maybe a pre-diabetic condition of diabetes mellitus, has been deemed as new matter. Support for said amendment wherein said chronic condition is a pre-diabetic condition of diabetes mellitus has not been found in the instant specification and therefore constitutes new matter.

Claim Rejections - 35 USC § 112-Second

Response to Arguments:

Applicant's arguments, filed 9/18/2007, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments. Therefore the rejctions have been withdrawn.

The following rejection is being newly applied and has been necessitated by amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15, 33 and all claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, and 33 comprise the wording "wherein said state of glucose metabolism disorder comprises a chronic condition," then states that the two types of **chronic conditions** are a diabetic and a pre-diabetic condition of diabetes mellitus, which is vague and indefinite. It is unclear as to what is meant by a chronic pre-diabetic condition of diabetes mellitus refers. Clarification via clearer claim wording is required.

Claim Rejections - 35 USC § 101

Response to Arguments

Applicant's arguments, filed 9/18/2007, with respect to the rejection of claims under 35 USC 101 for being drawn to non-statutory subject matter have been fully considered and are persuasive because of applicant's amendment. Therefor the rejection has been withdrawn.

Claim Rejections - 35 USC § 102

Response to arguments:

Applicant's arguments, filed 9/18/2007, with respect to rejection of claims Under 35 USC 102 (a) and 35 USC 102 (e) have been fully considered and are persuasive

because of applicant's amendments and arguments. Therefore the rejections have been withdrawn.

The following rejection is being newly made and necessitated by amendment:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 8-16, 21-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalatz et al. (US P/N 6925393) in view of Proniewicz et al. (US P/N 6853854).

Claims are drawn to a method for screening a subject for disorders of glucose metabolism, comprising measuring a glucose concentration profile, said glucose concentration profile comprising a plurality of blood glucose concentrations from at least after a glucose or meal challenge; generating a screening factor, wherein said screening factor comprises a mathematical representation of at least a plurality of glucose concentrations within said glucose concentration profile, wherein said screening factor is uniquely associated with a state of glucose metabolism disorder and classifying the subject into one of said states of glucose metabolism disorder based on evaluation of said screening factor, wherein said screening factor comprises an abstract representation of said glucose profile.

Kalatz et al. teaches limitations of claims 1, 2, 5, 22, 28, 30, and 32 in the Abstract, in Fig. 3, and at col. 3, lines 66-67 and col. 4, lines 1-19, col. 7, lines 65-67, col. 8, lines 1-8, and col. 9, lines 34-54. Kalatz et al. in the Abstract teaches measuring a glucose profile, which comprises a time series and evaluating the profile according to at least one profile. Kalatz et al. further teaches at Fig. 3, generating a curve for representing a plurality of glucose concentrations, which reads on a mathematical representation of at least a plurality of glucose concentrations within said glucose concentration profile. Additionally, the graph can be used as a screening factor for determining the state of the patient during the analysis, which reads on a screening factor comprising of a representation of a shape of said glucose concentration profile. Kalatz et al. in the abstract describes patients who have a chronic stat of glucose metabolism disorder such as diabetes mellitus and that the invention is to classify those patients based on their blood glucose levels and meals consumed. Therefore, the cited invention does classify a patient's blood glucose level as being within the limits of such a state and determines the necessary insulin dosage based on the determined blood glucose level. Furthermore, Kalatz et al. at col. 7, lines 65-67, col. 8, lines 1-8 and col. 9 that a screening factor is used to determine the state of the subject, which may be a hypoglycemic or hyperglycemic state, which reads on classifying a subject into a pre-diabetic condition of diabetes mellitus. Additionally the system comprises a warning signal from a warning unit if the state of the subject lies outside the state of "normal," which reads on an abstract representation of said glucose concentration profile. Kalatz et al. at col. 4, lines 5-9, discusses hypoglycemic and hyperglycemia as predetermined

classes where a subject would be classified as cited by the claims and reads on an unsupervised classification using a screening factor. Furthermore, the analyzers taught by Kalatz et al. read on the broadly interpreted claim language of a pattern recognition system. Kalatz et al. teaches, in Fig. 3, parts of claim 5 wherein a parameter includes an area under the curve and over a defined period of time along with a maximum glucose concentration and a glucose concentration after an elapse of a predetermined time interval.

Kalatz does not specifically teach a noninvasive analyzer for obtaining glucose values, but does teach the other limitations of a minimally and invasive blood glucose analyzer.

Proniewicz et al., at col. 2, lines 1-67, teaches using a noninvasive analyzer for obtaining glucose values and describes its advantage to reducing the possibility of infection and unseemly scarring, which are some of the risks involved in blood withdrawl.

It would have been obvious to one of ordinary skill in the art at the time of the instant application to combine the methods for obtaining and evaluating glucose profiles taught by Kalatz et al. with obtaining glucose values noninvasively as taught by Proniewicz et al. because it is a procedure that has been desirable to have and would be obviously more favorable to many patients who may benefit from this technology by reducing the risk for infection and unseemly scarring.

Kalatz et al. teaches limitations of claim 3 at col.7, lines 43-45, where Kalatz discusses actual values of blood glucose concentrations.

Kalatz et al. teaches limitations of claims 4, 8, and 9 at col. 7, lines 22-42. Kalatz et al. discusses how glucose values are proportionate, or relative as cited in the claim, to insulin amounts and are calculated accordingly on a linear scale.

Kalatz et al. teaches limitations of claim 6 ~~is taught by Kalatz et a~~l. at col. 3, lines 66-67, col. 4, lines 1-19, col. 7, lines 65-67, and col. 8, lines 1-21. Kalatz et al. discusses a range of normal values and outside this range calls for a warning signal to the subject as being in an abnormal condition. The administration of insulin discussed by Kalatz et al. is indicative of a subject who is diabetic.

Kalatz et al. teaches limitations of claims 10-14 and 25-27 at col. 7, lines 60-65, col. 9, lines 5-67 and col. 10, lines 1-20. Kalatz et al. teaches a pre-determined threshold value for a weighting factor, which includes the the possibility of assigning the weighting factor a value of zero. Claim 25 comprises several alternative limitations, such as a noninvasive, minimally invasive, and invasive blood glucose analyzer. Kalatz et al. teaches a minimally and invasive blood glucose analyzer.

Kalatz et al. teaches limitations of claims 15-16 and 29 as described above for claim 1 and at col. 7, lines 60-65, col. 9, lines 5-67 and col. 10, lines 1-20. Kalatz et al. at col. 9, lines 52-60 discusses using empirical studies to supplement data for determining a parameter value, which reads on wherein missing data are supplied from historical data for determining parameter and/or weighting values

Kalatz et al. teaches limitations of claim 21 at col. 3, lines 66-67 and col. 4, lines 1-19.

Kalatz et al. teaches limitations of claims 23-24 at col. 8, lines 9-21 and col. 10, lines 15-20. Kalatz et al. discusses advising the subject of screening results through a display which advises the subject on the amount of insulin to administer and allowing the patient to control the concentration levels.

Kalatz et al. teaches limitations of claim 33 as described above for claim 1 and at col. 9, lines 5-54. Kalatz et al. discloses an evaluation unit, which generates a screening factor which can be a curve that is used by the evaluation unit to determine the glucose state of the patient, which reads on a screening factor comprised of a result of a supervised classification, wherein the evaluation unit performs the supervised classification in its determination of the glucose state based on the generated graph.

Claims 1-16, 21-26, 29-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otvos et al. (US P/N 6,518,069) in view of Proniewicz et al. (US P/N 6853854).

Claims are drawn to a method for screening a subject for disorders of glucose metabolism, comprising measuring a glucose concentration profile, said glucose concentration profile comprising a plurality of blood glucose concentrations from at least after a glucose or meal challenge; generating a screening factor, wherein said screening factor comprises a mathematical representation of at least a plurality of

glucose concentrations within said glucose concentration profile, wherein said screening factor is uniquely associated with a state of glucose metabolism disorder and classifying the subject into one of said states of glucose metabolism disorder based on evaluation of said screening factor.

Otvos et al. teaches limitations of claims 1-6, 15-16, 22, 23, 28, and 33 at the abstract, Fig. 1, Fig. 2, col. 2, lines 45-50 and lines 55-65, col. 3, lines 38-55, at col. 4, lines 12-35, and at col. 8 lines 55-67. Otvos et al. describes deriving a reference spectrum from NMR for a known glucose concentration sample, which reads on measuring a glucose concentration profile. Otvos et al. further describes obtaining a patient blood sample and determining the glucose concentration, which inherently the blood sample is taken at some point after a glucose or meal challenge, which the claims are broadly interpreted as meaning at any point after a glucose or meal challenge. Otvos et al. teaches deriving a NMR data set from the blood sample that is used to evaluate the blood sample for screening for diabetes, which reads on generating a screening factor that is a mathematical representation of at least a plurality of glucose concentrations within said glucose profile and is uniquely associated with a state of glucose metabolism disorder and classifying the subject into one of said states of glucose metabolism disorder on evaluation of said screening factor. Otvos et al. at the abstract further describes an associated glucose metabolism disorder as diabetes mellitus. Furthermore, the analyzers taught by Otvos et al. read on the broadly interpreted claim language of a pattern recognition system. Otvos et al. at col. 4, teaches blood glucose concentrations comprise a time series, are actual values, relative

values, and wherein said screening factor is generated using a parameter, wherein said parameter includes maximum glucose concentrations and an area under the curve of the glucose profile as in Fig. 1. Otvos et al. also describes classifying by comparing said screening factor with a corresponding predetermined value and/or a range of values indicative of either a normal condition or one of a plurality of abnormal conditions. Otvos et al. teaches at col. 4, lines 18-23 using referenced coefficients for actual or relative values when generating an evaluation factor, which reads on a screening factor that uses actual or relative values for parameters and weights. Otvos et al. at col. 8 discloses acquiring reference data to further evaluate blood levels, which reads on missing data that is supplied from historical data. Otvos et al., at col. 3, discloses the use of an NMR-based analysis to generate the screening factor and classify the patient, which reads on a supervised classification of the screening factor.

Otvos does not specifically teach a noninvasive analyzer for obtaining glucose values, but does teach the other limitations of a minimally and invasive blood glucose analyzer.

Proniewicz et al., at col. 2, lines 1-67, teaches using a noninvasive analyzer for obtaining glucose values and describes its advantage to reducing the possibility of infection and unseemly scarring, which are some of the risks involved in blood withdrawl.

It would have been obvious to one of ordinary skill in the art at the time of the instant application to combine the methods for obtaining and evaluating glucose profiles taught by Otvos et al. with obtaining glucose values noninvasively as taught by

Proniewicz et al. because it is a procedure that has been desirable to have and would be obviously more favorable to many patients who may benefit from this technology by reducing the risk for infection and unseemly scarring.

Otvos et al. teaches claims 8-14, 21-22, and 25-26 at col. 8 – col. 14. Otvos et al. describes determining the scaling parameters (i.e. weighting values) on a linear or non-linear scale and using pre-determined threshold values. Otvos et al. discloses a computer programmed for executing the said method steps.

Otvos et al. teaches claim 23 and 24 at col. 15, lines 25-33. Otvos et al. teaches generating a report that includes all the screening information and results and discusses throughout the specification of the results being given to the doctor, who will inherently advise the patient on the screening results and health risks.

Otvos et al. teaches claim 29, 30, and 32 at Fig. 1 and Fig. 2. Otvos et al. teaches the screening factors, which are NMR values, which show numerical values and representations of a shape of said glucose concentration profiles by the shape of the graphs.

Double Patenting

Response to arguments:

The rejection of claims under a provisional double patenting rejection has been withdrawn because applicant's filing of a terminal disclaimer.

Allowable Subject Matter

Claim 17 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Claims 1-6, 8-16, 21-26, 28-30, 32, and 33 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

MICHAEL BORIN, PH.D
PRIMARY EXAMINER